May 28, 2003

C. Judith Michaels
Technical Contact
Henkel Loctite
1001 Trout Brook Crossing
Rocky Hill, CT 06067

Dear Ms. Michaels:

The Office of Pollution Prevention and Toxics is transmitting EPA's comments on the robust summaries and test plan for Ethyl Cyanoacrylate posted on the ChemRTK HPV Challenge Program Web site on January 28, 2003. I commend Henkel Loctite for its commitment to the HPV Challenge Program.

EPA reviews test plans and robust summaries to determine whether the reported data and test plans will provide the data necessary to adequately characterize each SIDS endpoint. On its Challenge Web site, EPA has provided guidance for determining the adequacy of data and preparing test plans used to prioritize chemicals for further work.

EPA will post this letter and the enclosed comments on the HPV Challenge Web site within the next few days. As noted in the comments, we ask that Henkel Loctite advise the Agency, within 60 days of this posting on the Web site, of any modifications to its submission.

If you have any questions about this response, please contact Richard Hefter, Chief of the HPV Chemicals Branch, at 202-564-7649. Submit questions about the HPV Challenge Program through the "Contact Us" link on the HPV Challenge Program Web site pages or through the TSCA Assistance Information Service (TSCA Hotline) at (202) 554-1404. The TSCA Hotline can also be reached by e-mail at tsca-hotline@epa.gov.

I thank you for your submission and look forward to your continued participation in the HPV Challenge Program.

Sincerely,

-S-

Oscar Hernandez, Director
Risk Assessment Division

Enclosure

cc: A. Abramson
W. Penberthy
M. E. Weber

EPA Comments on Chemical RTK HPV Challenge Submission:
Ethyl Cyanoacrylate

Summary of EPA Comments

The sponsor, Henkel Loctite Corporation, submitted a test plan and robust summaries to EPA for Ethyl cyanoacrylate (CAS No. 7085-85-0) dated December 20, 2002. EPA posted the submission on the ChemRTK HPV Challenge Web site on January 28, 2003.

EPA has reviewed this submission and has reached the following conclusions:

1. Physicochemical Properties. Adequate data are available for melting point, partition coefficient and water solubility. The submitter needs to provide data for vapor pressure and additional information to justify not testing for boiling point.

2. Environmental Fate. Adequate data are available for biodegradation and fugacity. The submitter needs to provide model estimates for indirect photodegradation and to revise the robust summary for stability in water.

3. Health Effects. Adequate data are available for the acute and genetic toxicity endpoints for the purposes of the HPV Challenge Program. EPA agrees that no further testing is necessary because of high reactivity and rapid polymerization in the presence of water.

4. Ecological Effects. Aquatic toxicity testing appears infeasible and unlikely to provide useful data.

EPA requests that the submitter advise the Agency within 60 days of any modifications to its submission.

EPA Comments on the Ethyl Cyanoacrylate Challenge Submission

Test Plan

Physicochemical Properties (melting point, boiling point, vapor pressure, partition coefficient and water solubility)

EPA agrees with the submitter's proposal that adequate date are available for melting point, water solubility, and partition coefficient.

Boiling Point. According to OECD TG 103, boiling point should be measured at ambient pressure (1 atm). However, the data provided by the submitter appears to be at reduced pressure (~ 2 mmHg). Therefore, the submitter needs to provide a rationale for measuring the boiling point at a reduced pressure or conduct a study according to OECD TG 103.

Vapor Pressure. The submitter needs to provide an acceptable vapor pressure at 25 deg C. The submitted value of < 2 torr at 25 °C is imprecise and inadequately documented. Because there are several boiling point measurements at varying temperatures available from the literature (EPA readily identified four), either a measured value following OECD TG 104 or an extrapolation value from a program such as NOMO5 would be acceptable.

Environmental Fate (photodegradation, stability in water, biodegradation, fugacity)

EPA agrees with the submitter that adequate date are available for biodegradation and fugacity.

Photodegradation. The submitter should consider providing AOPWIN model results to support the value reported in the robust summary for the methyl homolog.

Stability in Water. The test plan discusses hydrolysis only by implication. The robust summary should state that it is rapid polymerization, rather than insolubility, that "precludes any attempt to measure...stability in water."

Health Effects (acute toxicity, repeated-dose toxicity, genetic toxicity, and reproductive/developmental toxicity)

Adequate data are available for the acute and genetic toxicity endpoints for the purposes of the HPV Challenge Program. The chemical had been considered for reproductive and developmental toxicity, inhalation neurotoxicity, and carcinogenicity testing; however, as noted by the submitter, the National Toxicology Program (NTP) recommended no further testing for ethyl cyanoacrylate given its rapid polymerization in presence of water and the inability to generate a stable aerosol[1]. EPA agrees that no further testing is necessary.

Genetic Toxicity. The genetic toxicity data were from unpublished reports by NTP. However, the submitter needs to provide these data in the form of robust summaries.

Ecological Effects (fish, invertebrates, and algae)

Because this chemical polymerizes to water-insoluble substances, it is not expected to be toxic to aquatic organisms at levels of its occurrence in water. Testing in this case appears infeasible as well as unnecessary for purposes of the HPV Challenge program.

Specific Comments on the Robust Summaries

Physicochemical Properties.

The submitter needs to provide references for the melting and boiling points.

Boiling Point. The submitter needs to state the pressure at which measured in the robust summary.

Followup Activity

EPA requests that the submitter advise the Agency within 60 days of any modifications to its submission.

References

1. NTP BSC (National Toxicology Program Board of Scientific Counselors). 1998. Meeting Agenda/Summary. Research Triangle Park, North Carolina. Available at: http://ntp-server.niehs.nih.gov/htdocs/liason/bsc_Feb5.html.